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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|---------------------|
| 10/518,980 | 05/31/2005 | Luigi De Ambrosi | SER-102.1P US | 2926 |
| 7590 | 08/30/2006 | | EXAMINER | |
| Leon R Yankwich Yankwich & Associates 201 Broadway Cambridge, MA 02139 | | | | KRISHNAN, GANAPATHY |
| | | | ART UNIT | PAPER NUMBER |
| | | | | 1623 |

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/518,980 | DE AMBROSI ET AL. |
| | Examiner | Art Unit |
| | Ganapathy Krishnan | 1623 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 December 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-10 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-5,7,9 and 10 is/are rejected.
 7) Claim(s) 6 and 8 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 10/24/2005

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because applicants have filed the first page of the WIPO publication for the abstract. It should be typed on a separate sheet of paper. Correction is required. See MPEP § 608.01(b).

In the preliminary amendment to the claims of 12/21/2004, at page 3, the title should be “We Claim” or “What is claimed is”. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3 and 7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 5 of U.S. Patent No. 7,091,337 ('337

patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 1 is drawn to a process for depolymerizing glycosaminoglycans comprising exposing the glycosaminoglycan to electron-beam radiation. Claim 1 of the '337 patent is also drawn to the same process using a high-energy radiation.

Instant claims 3 and 7 recite limitations wherein heparin is the glycosaminoglycan and specific organic compounds in the presence of which the process is carried out. Claims 2 and 5 of the '337 patent also recite the same limitations.

It would have been obvious to one of ordinary skill in the art that instant claims 1, 7 and 7 are substantially overlapping with claims 1, 2 and 5 of the '337 patent. One of ordinary skill in the art would be motivated to perform the process as instantly claimed since the starting material and solvents are the same and the process would be expected to depolymerize the glycosaminoglycan when irradiated with high-energy radiation like electron beam.

Instant claims 1, 3 and 7 must recite limitations that are patentably distinct from those of claims 1, 2 and 5 of the '337 patent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Cho et al (KR 20000036332, English Abstract).

Cho et al teach preparation of low molecular weight heparin by exposing an aqueous solution of high molecular weight heparin using electron beam. This is seen to meet the limitations of instant claims 1, 3 and 5.

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by De Ambrosi et al (US 4,987,222).

De Ambrosi et al teach depolymerized glycosaminoglycans obtained via irradiation (see examples, col. 5, line 45 through col. 7, line 20).

Claim 10 is a product-by-process claim. “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al (KR 20000036332, English Abstract).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 is drawn to a process of depolymerization of a glycosaminoglycan by exposing it to electron beam, wherein the process involves dynamic irradiation. Claims 4 and 9 recite limitations drawn to energy and dosage of the radiation.

Cho et al teach preparation of low molecular weight heparin by exposing an aqueous solution of high molecular weight heparin via to an electron beam. Even though Cho does not specifically state that his process involves dynamic irradiation, the specific dosage or energy of the radiation it would have been obvious to perform the process wherein the solution containing the glycosaminoglycan is fluxing as a thin stream in front of the electron beam source. It is well within the purview of one of ordinary skill in the art to adjust the dosage and the energy of the radiation used for the purpose of optimization.

One of ordinary skill in the art would be motivated to perform the process using dynamic irradiation as instantly claimed since such a process, which is similar to a continuous process, would allow for preparation of large amounts depolymerized heparin in a shorter time period.

Conclusion

1. Claims 1-5, 7 and 9-10 are rejected.
2. Claims 6 and 8 drawn to a process for the depolymerization of a glycosaminoglycan comprising irradiation with an electron beam in the presence of specific class of organic compounds, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten

in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK



8/11/06
Shaojia Jiang
Supervisory Patent Examiner
Art Unit 1623